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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,581	06/23/2003	Michelle M. Hanna	2072.0010002	8564

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EXAMINER	
KIM, YOUNG J	
ART UNIT	PAPER NUMBER
1637	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/600,581	HANNA, MICHELLE M.	
	Examiner	Art Unit	
	Young J. Kim	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 December 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *55-84,106-111,113,114 and 130-148* is/are pending in the application.

4a) Of the above claim(s) *72-84,106-111,136,137 and 141* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *55-71,113,114,130-135,138-140 and 142-148* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/13/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The present Office Action is responsive to the Amendment received on December 13, 2006.

Preliminary Remark

Claims 1-54 have been canceled.

Claims 55-84, 106-111, 113, 114, and 130-148 are pending of which, claims 72-84, 106-111, 136, 137, and 141, remain withdrawn as being drawn to non-elected inventions, non-election of which was made with traverse.

Claims 55-71, 113, 114, 130-135, 138-140, and 142-148 are under prosecution herein.

Information Disclosure Statement

The IDS received on December 13, 2006 is acknowledged.

A signed copy of the PTO/SB form is enclosed herewith.

Claim Objections

The objection to claims 131-133 and 135 for being dependent on withdrawn claims 72 and 106 (i.e., non-elected invention)[1], made in the Office Action mailed on June 14, 2006 is withdrawn in view of the Amendment received on December 13, 2006.

The objection to claims 142-144 for being dependent on withdrawn claim 141, made in the Office Action mailed on June 14, 2006 is also withdrawn in view of the Amendment received on December 13, 2006.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 63, 70, 71, 114, 131-133, 135, 138-140, and 142-148 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter, made in the Office Action mailed on June 14, 2006 is withdrawn in view of the Amendment received on December 13, 2006.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 55, 57-59, 61-68, 70, and 131-135 under 35 U.S.C. 102(b) as being anticipated by Sasaki et al. (PNAS USA, March 1998, vol. 95, pages 3455-3460; IDS reference), made in the Office Action mailed on June 14, 2006 is maintained for the reasons already of record.

Applicants' arguments presented in the Amendment received on December 13, 2006 have been fully considered but they are not found persuasive for the reasons set forth in the, "Response to Arguments," section.

The Rejection:

Sasaki et al. disclose a transcriptional sequencing method, said method comprising the steps:

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[1] Claims 131-133 and 135 are multiple dependent claims which are dependent on elected inventions as well as non-elected invention. Thus claims are examined to the extent of their dependency on the elected invention.

a) hybridizing a single stranded target polynucleotide with an abortive promoter cassette comprising a sequence that hybridizes to the a single-stranded target polynucleotide, and a region that can be detected by transcription by a polymerase (Figure 4, see primer comprising a sequence complementary to the target nucleic acid, and a region which is a T7 promoter or T3 promoter, which is recognized by a polymerase);

b) incubating said target polynucleotide with an RNA polymerase (with T7 or T3 RNA polymerase; see Figure 4), an initiator (or 1mM GMP; see page 3456, 2nd column, bottom paragraph) and a terminator (fluoresecent dye terminator; see page 3457, 1st column, bottom paragraph);

c) synthesizing oligonucleotide transcripts that is complementary to the initiation start site of the abortive promoter cassette, until dye terminator is incorporated in to the transcription product (see page 3457, Figure 4);

d) detecting the oligonucleotide transcripts by electrophoresis sequencing method (see Figure 5; page 3460, 1st column).

The limitation, "abortive promoter sequence" is not specifically defined by the instant specification what is considered to be an "abortive promoter cassette," and since the claim does not recite a structure of such a cassette, based on a reasonable broadest interpretation of the claim, any structure which comprises promoter sequence that is capable of effecting abortive reiterative synthesis, is deemed to meet this limitation, there by clearly anticipating claim 55.

With regard to claims 57-59, 64, and 134, the detection is achieved by the use of a modified nucleotide (fluorescent dye terminator; *see* page 3460, 1st column), particularly tetramethyl rhodamine (or TMR) (page 3456, Figure 2).

With regard to claims 61 and 62, the RNA polymerase is a T7 or T3 RNA polymerase (Figure 4; page 3455, 2nd column, bottom paragraph).

With regard to claim 63, the transcripts being produced would be met by the transcripts produced by Sasaki et al.

With regard to claims 65, 68, 135, the initiator is at least one nucleotides in length (dNTPs).

With regard to claim 66, the single-stranded target polynucleotide is DNA (page 3456, 2nd column, 2nd paragraph).

With regard to claim 67, one of the nucleotides are dUTP (page 3456, 1st column).

With regard to claim 70, the primer comprising the T7 or T3 promoter sequence has at least one nucleotide which hybridizes to the single-stranded target polynucleotide. Since the term, "linker" does not preclude a nucleotide, the primer of Sasaki et al. would anticipate this limitation.

With regard to claims 131-133, the primer of Sasaki et al. comprises nucleotide sequences which are complementary to the target polynucleotide. Whether such sequences would form a bubble complex or not, it is asserted that when an RNA polymerase binds to said region, a bubble formation would occur (as in any transcription reaction).

Therefore, Sasaki et al. clearly anticipate the invention as claimed.

Applicants are advised that amending the claims to clearly recite the structure of the "abortive promoter cassette" as exemplified in Figure 19 would overcome the instant rejection.

Response to Arguments:

Applicants' traverse the rejection based on the disclosure found in the instant specification.

Applicants contend that the claims need not be amended to explicitly recite the structure of APC (abortive promoter cassette) because the specification already, "sets forth what is encompassed by the limitation 'abortive promoter cassette' (APC)." (page 23, 3rd paragraph, Response).

This argument is not found persuasive.

As Applicants are fully aware, MPEP 2106(II)(C) states that while it is appropriate to use the specification to determine what applicant intends a term to mean, a positive limitation from the specification ***cannot be read into a claim that does not impose that limitation***.

In addition, MPEP 2106(II)(C), explicitly states that the claims are given their broadest reasonable interpretation:

> "Office personnel are to give claims their broadest reasonable interpretation in light of the supporting disclosure. In re Morris, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997). ***Limitations appearing in the specification but not recited in the claim are not read into the claim.*** > E-Pass Techs., Inc. v. 3Com Corp., 343 F.3d 1364, 1369, 67 USPQ2d 1947, 1950 (Fed. Cir. 2003) (claims must be interpreted "in view of the specification" without importing limitations from the specification into the claims unnecessarily).< In re Prater, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-551 (CCPA 1969). See also In re Zletz, 893 F.2d 319, 321-22, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989) ("During patent examination the pending claims must be interpreted as broadly as their terms reasonably allow.... The reason is simply that during patent prosecution when claims can be amended, ambiguities should be recognized, scope and breadth of language explored, and clarification imposed.... An ***essential purpose of patent examination is to fashion claims that are precise, clear, correct, and unambiguous***. Only in this way can uncertainties of claim scope be removed, as much as possible, during the administrative process.").

Applicants contend that the abortive promoter cassette (APC) is defined in the specification on page 14-15.

It is respectfully pointed that while the specification describes what an APC could have, it does not limit in any way that APC is limited to this structure:

> "Abortive Promoter Cassettes (APC) are regions of nucleic acid that form a polymerase binding site and can be attached to other macromolecules through interaction with a specific nucleic acid sequence, which is termed APC linker. APC linker *can be* attached..." (page 14, section [0036])

Clearly, the specification defines the term, "APC" as that which bears regions of nucleic acid that forms a polymerase binding site and can be attached to other molecules through ***any*** interaction with a specific nucleic acid sequence. Structurally, an APC need only have regions of nucleic acid that forms a polymerase binding site and that which ***can*** be attached to other molecules.

The later section description found on page 15, recites that the APC contains two regions of essential complementarity, as already set forth, the specification does not state that an APC be limited to this structure. A specific definition must use a language such as, "by APC, we mean" or "APC is limited to.." which clearly conveys to a reader that the definition limits the term to that which is described in the description.

Absent such a definition, and absent an art-accepted explicit definition, a generic claim term employed by Applicants are to be given the broadest reasonable interpretation.

Applicants refer to page 23-25 of the instant specification for supporting their position that the term, "APC" is explicitly defined.

It is respectfully pointed out that on page 55 of the instant specificatoin, an APC is defined as that which forms a self-complementary sequence of DNA that may consist of two partially complementary upper and lower oligonucleotides that form a single-stranded bubble complex regions comprising a defined site from which an initiator and a suitable RNA polymerase can synthesize an abortive oligonucleotide product; or two complementary oligonucleotides that form a transcription bubble region in the presence of an RNA polymerase, which allows for the synthesis of an abortive oligonucleotide product (section [0151]).

In other words, an APC can simply be a double stranded nucleic acid from which RNA polymerase ***can*** synthesize a transcript from as any double stranded nucleic acid would form a bubble complex when RNA polymerase is bound thereto.

Simply put, there is no structural requirement by the term, "APC" other than a generic requirement that it must form a self-complementary form (whether from a single oligonucleotide or two separate oligonucleotides), where upon if RNA polymerase is bound, ***can form*** a bubble complex (which would be any double stranded nucleic acid).

The claims do not even require the essential element of an APC which may allow the RNA polymerase to bind thereto.

Such generic limitation cannot properly delimit the claims so as to properly preclude application of prior art which may not be relevant to the claimed invention.

As pointed out in *In re Mott*, 190 U.S.P.Q. 536 (CCPA 1975), "Claims must be given broadest reasonable construction their language will permit in ex parte prosecution, and applicant who uses broad language runs the risk that others may be able to support the same claim with a different disclosure."

Sasaki et al. disclose two primers comprising a T7 promoter sequence appended at the end of said primers, which "hybridizes" to the target nucleic acid sequences, and forms a ***double*** stranded nucleic acid comprising T7 and T3 promoter sequences. Said double stranded nucleic acid is transcribed by an RNA polymerase which will result in the formation of the bubble complex.

Clearly, the disclosure of Sasaki et al. clearly meets the claim limitation based on the reasonable broadest interpretation of the claimed term, "APC."

Applicants had been advised that *clear* recitation of what an APC is, by reciting the structural limitation in the actual claims would overcome the rejection.

Applicants next contend that the according to Applicants' specification, the term, "reiterative" refers to "multiple identical or highly similar copies of a sequence of interest (page 24, 3rd paragraph, Response).

This definition appears to an explicit definition, which would limit the claim term.

However, it is respectfully submitted that the disclosure of Sasaki et al. meets the definition of the claim term in every way.

It is true that Sasaki employ four dye-dNTP terminators, generating sequencing products that are heterogeneous in size. However, if Applicants are contending that the sequence products generated by Sasaki et al. are unique and not a single products are duplicates, Applicants' position must be substantially proved by evidence. It's an art accepted fact that when dye-termination sequencing products are formed, there occurs same sequencing products which are terminated at the same nucleotide position. If such were not true, the sensitivity of the sequencing would suffer.

The word, "multiple" requires at least two entities. It is respectfully submitted that the sequencing products of Sasaki et al. contains at least two sequencing products which are terminated at the same position.

In addition, as Applicants' definition clearly states, reiterative refers to "multiple identical ***or*** highly similar copies of a sequence of interest.

While the sequencing products may be heterogeneous (in terms of their size), all of the sequencing products are highly similar to the template from which they are derived.

Hence, the method disclosed by Sasaki et al. clearly anticipate the invention as claimed.

The rejection is proper and thus maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the

> subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The rejection of claims 56, 57-71, 113, 114, 130-135, 138-140, and 142-148 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sasaki et al. (PNAS USA, March 1998, vol. 95, pages 3455-3460; IDS reference) in view of Kang et al. (U.S. Patent No. 6,268,131, issued July 31, 2001), made in the Office Action mailed on June 14, 2006 is maintained for the reasons already of record.

Applicants do not present any new arguments for the instant rejection other that those which were fully addressed above.

Therefore, the rejection is maintained for the reasons already of record as well as for the reasons provided above.

The Rejection:

Sasaki et al. disclose a transcriptional sequencing method, said method comprising the steps:

a) hybridizing a single stranded target polynucleotide with an abortive promoter cassette comprising a sequence that hybridizes to the a single-stranded target polynucleotide, and a region that can be detected by transcription by a polymerase (Figure 4, see primer comprising a sequence complementary to the target nucleic acid, and a region which is a T7 promoter or T3 promoter, which is recognized by a polymerase);

b) incubating said target polynucleotide with an RNA polymerase (with T7 or T3 RNA polymerase; see Figure 4), an initiator (or 1mM GMP; see page 3456, 2nd column, bottom paragraph) and a terminator (fluoresecent dye terminator; see page 3457, 1st column, bottom paragraph);

c) synthesizing oligonucleotide transcripts that is complementary to the initiation start site of the abortive promoter cassette, until dye terminator is incorporated in to the transcription product (see page 3457, Figure 4);

d) detecting the oligonucleotide transcripts by electrophoresis sequencing method (see Figure 5; page 3460, 1st column).

The limitation, "abortive promoter sequence" is not specifically defined by the instant specification what is considered to be an "abortive promoter cassette," and since the claim does not recite a structure of such a cassette, based on a reasonable broadest interpretation of the claim, any structure which comprises promoter sequence that is capable of effecting abortive reiterative synthesis, is deemed to meet this limitation.

Sasaki et al. do not explicitly disclose that their method would be used in the detection of pathogens in a sample, such as RNA virus, or that an RNA dependent RNA polymerase is used for the transcription, or that the RNA dependent RNA polymerase is a poliovirus RNAP.

Kang et al. disclose a method of sequencing nucleic acid via use of RNA dependent RNA polymerases (column 9, lines 16-35 and 43-57), wherein the transcription of the template is initiated by a promoter sequence. An embodiment of the teachings of Kang et al. is drawn to the hybridization of the target nucleic acid to a primer which comprises a promoter sequence, wherein said primer is immobilized on a solid surface.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to apply the teachings of Sasaki et al. with the teachings of Kang et al. for the purpose of detection/characterizing pathogens (such as RNA virus) in a sample, for the well known benefit of survival of mankind.

Such benefit is clearly implied by Sasaki et al., wherein the artisans explicitly state that their method would be useful in diagnostics, clinical diagnosis and genome sequencing. Clearly, one of ordinary skill in the art would have recognized that clinical diagnosis would undoubtedly include detection of pathogens in clinical samples. Therefore, one of ordinary skill in the art would have been motivated to combine the teachings of Sasaki et al. with the teachings of Kang et al. so as to detect pathogens such as RNA-based pathogens. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success at producing the combination since both teachings relied on the template nucleic acid having a promoter sequence which is recognized by the RNA dependent RNA polymerase to initiate the transcription reaction, wherein the transcription reaction is terminated by the incorporation of a terminating nucleotide, thereby rendering claims 56, 71, 113, 114, 130, 138-140, and 142-148 obvious.

With regard to claims 57-59, 64, and 134, the detection is achieved by the use of a modified nucleotide (fluorescent dye terminator; *see* page 3460, 1st column), particularly tetramethyl rhodamine (or TMR) (page 3456, Figure 2).

With regard to claims 61 and 62, the RNA polymerase is a T7 or T3 RNA polymerase (Figure 4; page 3455, 2nd column, bottom paragraph).

With regard to claim 63, the transcripts being produced would be met by the transcripts produced by Sasaki et al.

With regard to claims 65, 68, 135, the initiator is at least one nucleotides in length (dNTPs).

With regard to claim 66, the single-stranded target polynucleotide is DNA (page 3456, 2nd column, 2nd paragraph).

With regard to claim 67, one of the nucleotides are dUTP (page 3456, 1st column).

With regard to claim 70, the primer comprising the T7 or T3 promoter sequence has at least one nucleotide which hybridizes to the single-stranded target polynucleotide. Since the term, "linker" does not preclude a nucleotide, the primer of Sasaki et al. would anticipate this limitation.

With regard to claims 131-133, the primer of Sasaki et al. comprises nucleotide sequences which are complementary to the target polynucleotide. Whether such sequences would form a bubble complex or not, it is asserted that when an RNA polymerase binds to said region, a bubble formation would occur (as in any transcription reaction).

For the reasons discussed above, the invention as claimed is *prima facie* obvious over the cited reference.

Applicants are advised that amending the claims to clearly recite the structure of the "abortive promoter cassette" as exemplified in Figure 19 would overcome the instant rejection.

Double Patenting

The rejection of claims 55-71, 113, 114, 130-135, 138-140, and 142-148 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-34 of U.S. Patent No. 7,045,319, made in the Office Action mailed on June 14, 2006 is withdrawn in view of the arguments presented in the Amendment received on December 13, 2006.

Specifically, Applicants' argument stating that the present claims are pursuing the claims which had been "restricted out" in its parent application, said parent application, which had been issued as the subject, U.S. Patent No. 7,045,319.

Hence, bar under 35 U.S.C. 121 applies and the obviousness-type double patenting has been withdrawn.

The provisional rejection of claims 55-71, 113, 114, 130-135, 138-140, and 142-148 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over pending (and/or elected) claims of copending Application No. 10/602,045; and 10/607,136, made in the Office Action mailed on June 14, 2006 is withdrawn in view of the arguments presented in the Amendment received on December 13, 2006.

Specifically, Applicants' argument stating that the present claims are pursuing the claims which had been "restricted out" in its parent application, said parent application, which had been issued as the subject, U.S. Patent No. 7,045,319.

Hence, bar under 35 U.S.C. 121 applies and the obviousness-type double patenting has been withdrawn.

With regard to the provisional rejection over the Application Serial No. 10/600,045, it appears that the application number was a typographical based on a duplicative recitation of the 10/602,045 application.

Hence, it is noted that there are no obviousness-type double patenting issues with 10/600,045 application.

Rejections, Maintained

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting

ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The provisional rejection of claims 55-71, 113, 114, 130-135, 138-140, and 142-148 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 26, 27, 103, 112, and 136-139 of copending Application No. 10/488,971 (herein, the '971 application), made in the Office Action mailed on June 14, 2006 is maintained for the reasons already of record.

Applicants do not present any arguments for the instant rejection and thus, the rejection is maintained.

The Rejection:

Although the conflicting claims are not identical, they are not patentably distinct from each other because claims of the '971 application are narrower species of method which renders the broader claims of the instant application in a genus-species anticipatory way.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The provisional rejection of claims 55-71, 113, 114, 130-135, 138-140, and 142-148 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-22, 32-34, and 44 of copending Application No. 10/976,240 (herein, the '240 application), made in the Office Action mailed on June 14, 2006 is maintained for the reasons already of record.

Applicants do not present any arguments for the instant rejection and thus, the rejection is maintained.

The Rejection:

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application and the claims of the '240 application require the same method of reiteratively synthesizing oligonucleotide transcripts which are terminated, as well as employing an abortive promoter cassettes.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The provisional rejection of claims 55-71, 113, 114, 130-135, 138-140, and 142-148 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11-27 of copending Application No. 10/425,037, made in the Office Action mailed on June 14, 2006 is maintained for the reasons already of record.

Applicants do not present any arguments for the instant rejection and thus, the rejection is maintained.

The Rejection:

Although the conflicting claims are not identical, they are not patentably distinct from each other because claims of the instant application and the claims of the '240 application require the same method of reiteratively synthesizing oligonucleotide transcripts which are terminated, as well as employing an abortive promoter cassettes.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed.

Applicants are **strongly advised** to amend claim 71 to make certain that the target polynucleotide that is being detected is single-stranded polynucleotide. This embodiment is supported in the drawings. IN addition, Applicants' reference submitted with the IDS received on December 13, 2006, in particular, reference NPL2 appears to disclose a ligation of bubble complex to a double-stranded polynucleotide template.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The Examiner is on flex-time schedule and can best be reached from 8:30 a.m. to 4:30 p.m (M-W and F). The Examiner can also be reached via e-mail to Young.Kim@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Gary Benzion, can be reached at (571) 272-0782.

Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (571) 273-8300. For Unofficial documents, faxes can be sent directly to the Examiner at (571) 273-0785. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Young J. Kim
Primary Examiner
Art Unit 1637
3/14/2007

YOUNG J. KIM
PRIMARY EXAMINER

YJK